

**IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF  
ALABAMA, NORTHERN DIVISION**

**JAMES STEADMAN, JR., as Personal  
Representative of the Estate of ROBERT  
EUGENE JONES, Deceased**

**PLAINTIFF,**

**v.**

**ETHEX CORPORATION, a foreign  
Corporation, and KV  
PHARMACEUTICAL COMPANY, a  
foreign Corporation,**

**DEFENDANTS.**

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**CASE NO. 2:09-cv-00773-CSC**

**ETHEX CORPORATION'S ORIGINAL ANSWER TO PLAINTIFF'S COMPLAINT**

COMES NOW ETHEX Corporation ("ETHEX") and files its Original Answer to Plaintiff's Complaint. ETHEX would respectfully show the Court the following:

1. ETHEX lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint and therefore denies them.

2. ETHEX lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore denies them.

3. Answering Paragraph 3 of the Complaint, ETHEX states that KV Pharmaceutical Company ("KV") is a Delaware for-profit corporation and is not licensed to do business in the State of Alabama. The remaining allegations in Paragraph 3 of the Complaint set forth legal conclusions to which no response is required. To the extent a response is required; ETHEX denies the remaining allegations in Paragraph 3 of the Complaint.

4. Answering the first sentence of Paragraph 4 of the Complaint, ETHEX states that KV manufactured prescription pharmaceutical products and supplied prescription pharmaceutical

products to ETHEX. Answering the second sentence of Paragraph 4, ETHEX states that the pharmaceutical products it marketed and distributed were supplied to it by KV.

5. Answering Paragraph 5 of the Complaint, ETHEX states that it is a Missouri for-profit corporation that is not licensed to do business in the State of Alabama; however ETHEX is licensed to distribute pharmaceutical products in the State of Alabama. The remaining allegations in Paragraph 5 set forth legal conclusions to which no response is required. To the extent a response is required ETHEX denies the remaining allegations in Paragraph 5 of the Complaint.

6. Answering Paragraph 6, ETHEX states that it marketed and distributed drugs manufactured by KV.

7. ETHEX denies the allegations in Paragraph 7 of the Complaint.

8. Answering Paragraph 8 of the Complaint, ETHEX states that on March 6, 2009, the Honorable Rodney W. Sippel of the United States District Court for the Eastern District of Missouri, Eastern Division, signed the "Consent Decree of Permanent Injunction" in the action styled Case No. 4:09-cv-0034: *United States of America v. KV Pharmaceutical Company, et al.* To the extent the allegations in Paragraph 8 quote, relate, or refer to other documents, those sources speak for themselves and any characterizations thereof are denied.

9. ETHEX denies the allegations in Paragraph 9 of the Complaint.

10. ETHEX denies the allegations in Paragraph 10 of the Complaint.

11. ETHEX denies the allegations in Paragraph 11 of the Complaint.

12. Answering Paragraph 12 of the Complaint, ETHEX states that it voluntarily recalled certain lots of Isosorbide Mononitrate Extended Release Tablets, 60 mg, including lot

number 58177-238-04. ETHEX further states that the tablets in lot number 58177-238-04 were manufactured by KV and marketed and distributed by ETHEX.

13. ETHEX lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of the Complaint and therefore denies them.

14. ETHEX denies the allegations in Paragraph 14 of the Complaint.

15. ETHEX denies the allegations in Paragraph 15 of the Complaint.

**COUNT I - AEMLD**

16. ETHEX incorporates its answers to Paragraphs 1 through 15 of the Complaint as if fully set forth herein.

17. ETHEX denies the allegations in Paragraph 17 of the Complaint.

18. ETHEX denies the allegations in Paragraph 18 of the Complaint.

19. ETHEX denies the allegations in Paragraph 19 of the Complaint.

20. ETHEX denies the allegations in Paragraph 20 of the Complaint.

**COUNT II – NEGLIGENCE & WANTONNESS**

21. ETHEX incorporates its answers to Paragraphs 1 through 20 of the Complaint as if fully set forth herein.

22. The allegations in the first sentence of Paragraph 22 set forth legal conclusions to which no response is required. To the extent a response is required; ETHEX denies the allegations in the first sentence of Paragraph 22. ETHEX denies the remaining allegations in Paragraph 22.

23. ETHEX denies the allegations in Paragraph 23 of the Complaint.

24. ETHEX denies the allegations in Paragraph 24 of the Complaint.

**COUNT III – BREACH OF EXPRESS WARRANTY**

25. ETHEX incorporates its answers to Paragraphs 1 through 24 of the Complaint as if fully set forth herein.

26. ETHEX denies the allegations in Paragraph 26 of the Complaint.

27. ETHEX denies the allegations in Paragraph 27 of the Complaint.

28. ETHEX denies the allegations in Paragraph 28 of the Complaint.

**COUNT IV – IMPLIED WARRANTY**

29. ETHEX incorporates its answers to Paragraphs 1 through 28 as if fully set forth herein.

30. ETHEX denies the allegations in Paragraph 30 of the Complaint.

31. ETHEX denies the allegations in Paragraph 31 of the Complaint.

32. ETHEX denies the allegations in Paragraph 32 of the Complaint.

33. Answering Plaintiff's Demands, ETHEX denies that Plaintiff is entitled to any of the relief he seeks.

34. To the extent that any allegations of Complaint have not been expressly admitted, such allegations are hereby denied.

**DEFENSES**

1. Plaintiff's Complaint fails to state a claim upon which relief may be granted.

2. In the event of remand, Defendant asserts that venue in the Circuit Court of Barbour County, Alabama, Clayton Division, is improper.

3. In the event of remand, Defendant asserts that venue in the Circuit Court of Barbour County, Alabama, Clayton Division, should be transferred under the doctrine of forum non conveniens.

4. Plaintiff cannot recover damages from ETHEX for any alleged manufacturing defect because ETHEX does not manufacture any pharmaceutical products.

5. Plaintiff's Complaint is barred for failure to join indispensable parties.

6. Plaintiff's claims are barred as a result of the decedent's own contributory negligence.

7. Plaintiff's alleged damages were caused by the decedent's own negligence or other fault.

8. Plaintiff's alleged damages were caused by the negligence or other fault of persons or entities other than ETHEX who are not within the control of ETHEX and for whom ETHEX has no liability.

9. Plaintiff's alleged damages resulted from independent, unforeseeable, superseding and/or intervening causes specific to the decedent and unrelated to any conduct of, or product placed in the stream of commerce by, ETHEX.

10. Plaintiff's warranty claims are barred by Alabama Code § 6-5-462.

11. Plaintiff is barred from proceeding both on claims for breach of warranty seeking compensatory damages and for tort claims seeking damages for wrongful death.

12. Plaintiff's alleged damages were the result of preexisting conditions specific to the decedent and unrelated to any conduct of, or product placed in the stream of commerce by, ETHEX.

13. To the extent any implied warranties would apply to Plaintiff, such warranties were disclaimed by Defendant.

14. Plaintiff's alleged damages were the result of the decedent's idiosyncratic reaction specific to him which ETHEX could not reasonably foresee and for which ETHEX is not responsible.

15. Plaintiff's alleged damages were caused in whole or in part by the decedent's misuse or unintended use of the product at issue.

16. Plaintiff's alleged damages were caused by changes or alterations made to the product by persons not within ETHEX's control.

17. Any claims made by Plaintiff are barred by the learned intermediary doctrine.

18. Plaintiff's product liability claims are barred because the benefits of the products outweighed their alleged risks.

19. The product at issue was designed, tested, manufactured and marketed in conformance with the state of the scientific, medical and technological art and knowledge existing at the time of sale and, accordingly, Plaintiff's claims are barred.

20. Plaintiff's claims are barred, in whole or in part, because ETHEX complied with all applicable statutes and with the requirements and regulations of the Food and Drug Administration.

21. Plaintiff's claims are pre-empted in whole or in part by the Federal Food, Drug & Cosmetic Act ("FDCA") and the regulations promulgated thereunder, the supremacy clause of Article VI of the United States Constitution, and/or federal and/or state laws and regulations governing the labeling, advertising, and sale of prescription pharmaceutical product at issue. Alternatively, ETHEX is entitled to a presumption that its product is not defective or unreasonably dangerous.

22. Plaintiff's claims against ETHEX are barred by Restatement (Second) of Torts Section 402A and the comments thereto.

23. Plaintiff's claims against ETHEX are barred by the Restatement (Third) of Torts: Product Liability §§ 2, 4, 6, 9, and 10 and the comments thereto.

24. Neither the decedent nor the decedent's respective physicians were induced to prescribe or use the product at issue based on any material representations or misrepresentations of ETHEX.

25. The decedent did not rely on any express or implied warranty allegedly made by ETHEX.

26. Plaintiff failed to mitigate any alleged damages.

27. The decedent suffered no physical injury proximately caused by, arising from or relating to the product at issue.

28. Plaintiff's causes of action may be barred, in whole or in part, by the doctrines of laches, waiver, and estoppel.

29. Plaintiff's causes of action may be barred, in whole or in part, by the applicable statute of limitations.

30. Plaintiff impermissibly seeks to impose liability on conduct protected from liability by the First Amendment to the United States Constitution and by Article 1, §4 of the Alabama Constitution.

31. In the absence of proof by Plaintiff that the product used and ingested by the decedent was made or distributed by ETHEX, ETHEX may not be held liable for any claim herein.

32. Any alleged danger associated with the use of the product at issue was open and obvious and Plaintiff is therefore barred from recovery.

33. The product at issue has certain unavoidable, inherent characteristics that cannot be obviated under the states of scientific knowledge existing at the time such product was manufactured. If the decedent sustained any injuries as a result of his use of or exposure to the product at issue, those injuries were the result of properties necessarily associated with the product that were unavoidable and for which ETHEX cannot be held responsible.

34. The product at issue has certain unavoidable, inherent characteristics. While denying that such characteristics are dangerous or defective, under the states of scientific knowledge at the time the product was manufactured, a practical and technically feasible alternative design that would have prevented the alleged harm was not available without substantially impairing the usefulness or intended purpose of the product at issue. Consequently, ETHEX did not act unreasonably in introducing the product at issue into trade or commerce.

35. Plaintiff has failed to state a legal or factual basis upon which a demand for an award for punitive damages against ETHEX can be predicated.

36. Imposition of punitive damages in this action would violate the Due Process Clause of the United States Constitution and the Due Process Clause of the Alabama Constitution.

37. The procedure and methods asserted for awarding punitive damages in this case violate the Due Process Clause of the United States Constitution and the Due Process Clause of the Constitution of the State of Alabama.

38. The claims of Plaintiff for punitive damages cannot be sustained because an award of punitive damages under Alabama law subject to no predetermined limit, such as a



maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose, would violate ETHEX's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process provisions of the Alabama Constitution.

39. The claims of Plaintiff for punitive damages cannot be sustained, because an award of punitive damages under Alabama law by a jury that (1) is not provided a standard sufficient for determining the appropriateness, or the appropriate size, of a punitive damages award, (2) is not instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status of a defendant, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary as to damages permissible, and (5) is not subject to judicial review on the basis of objective standards, would violate ETHEX's substantive and procedural due process and equal protection rights guaranteed by the Fourteenth Amendment to the United States Constitution and the double jeopardy clause of the Fifth Amendment as incorporated into the Fourteenth Amendment, and by the Alabama constitutional provisions providing for due process, equal protection, and guarantee against double jeopardy.

40. The claims of Plaintiff for punitive damages cannot be sustained because an award of punitive damages under Alabama law without proof of every element beyond a reasonable doubt would violate ETHEX's substantive and procedural due process rights under the Fourteenth Amendment to the United States Constitution and under the due process provisions of the Alabama Constitution.

41. Any award of punitive damages based on anything other than ETHEX's conduct in connection with the matters that are the subject of this lawsuit would violate the due process clause of the Fourteenth Amendment to the United States Constitution and the double jeopardy clause of the Fifth Amendment as incorporated into the Fourteenth Amendment and the Alabama constitutional provisions providing for due process and guarantee against double jeopardy, because any other judgment for punitive damages in this case cannot protect Defendants against impermissible multiple punishment for the same wrong.

42. Any award of punitive damages in this case would violate ETHEX's rights under the substantive and procedural due process clause of the United States Constitution and of the Constitution of the State of Alabama; the excessive fines clauses of the Eighth Amendment to the United States Constitution; the contract clause of Article Two of the United States Constitution; the equal protection clause of the United States Constitution and the Constitution of the State of Alabama.

43. The Alabama punitive damage system, on its face and as applied, violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution. While the Supreme Court of the United States perceived the system as constitutional in Pacific Mutual Life Insurance Co. v. Haslip, 499 U.S. 1 (1991), events subsequent to Haslip have shown that the system is wholly arbitrary, fundamentally unfair and utterly irrational in violation of due process. See Armstrong v. Roger's Outdoor Sports, Inc., 581 So. 2d 414, 423 (Ala. 1991) (Maddox, J., dissenting); Henderson v. Alabama Power Co., 627 So. 2d 878, 894-95 (Ala. 1993) (Maddox, J., dissenting); Id. at 914 (Houston, J., dissenting). The Alabama system affords juries standardless discretion to impose unlimited punishment, and review of such awards is constitutionally deficient. See Honda Motor Co., Ltd. v. Oberg, 114 S. Ct. 2331 (1994).

Alabama post-verdict review is neither meaningful, consistent nor constitutionally adequate to cure this crucial constitutional defect.

44. Alabama's punitive damage system, on its face and as applied, violates the Due Process Clause of the Fourteenth Amendment because there are absolutely no meaningful standards or limits for determining the amount of the award, contravening the deeply rooted American tradition that punishment may not be imposed in the absence of a pre-existing, express legislatively established range of penalties.

45. The imposition of a punitive damage award in this case in the absence of explicit, particularized guidelines or standards is highly unfair and constitutionally infirm because an award made in the absence of such guidelines or standards may be grossly excessive, disproportionate, arbitrary and irrational. A punitive damage award in the absence of such guidelines or standards will bear no rational or reasonable relationship to ETHEX's alleged conduct in this matter or to any alleged harm to Plaintiff, and will dwarf legislatively established fines for comparable conduct. A punitive damage award in the absence of such guidelines or standards therefore will violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution, and the excessive fines clause of the Alabama Constitution, Ala. Const. Art. I, § 15.

46. Without the protections previously provided in §§ 6-11-23(a) and 6-11-24, Code of Alabama, regarding punitive damage awards, now declared unconstitutional by the Alabama Supreme Court, the State of Alabama no longer affords to a defendant sufficient protection under the United States Constitution from excessive and arbitrary punitive damage awards.

47. A punitive damage award in this case will violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution, the Commerce Clause, the Equal

Protection Clause and the Privileges and Immunities Clause because the award would be based upon an Alabama state enforced policy that unconstitutionally discriminates against a defendant in punitive damages cases.

48. The imposition of punitive damages in this case based upon theories of respondent superior, agency, vicarious liability, or joint and several liability violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution.

49. Any award of punitive damages and damages for mental anguish or pain and suffering based on anything other than ETHEX's conduct would violate the due process clause of the Fourteenth Amendment to the United States Constitution and the double jeopardy clause of the Fifth Amendment as incorporated into the Fourteenth Amendment and the Alabama constitutional provisions providing for due process and guaranty against double jeopardy, because any other judgment for punitive damages in this case cannot protect Defendants against impermissible multiple punishment for the same wrong.

50. Alabama system and structure for punitive damage awards, together with the claims for punitive damages sought by Plaintiff in this lawsuit, constitute a violation of the due process clause of the Constitution of the United States, under authority of B.M.W. of North America, Inc. v. Gore, 116 U.S. 1589 (1996). The allegations made by the Plaintiff in this action, and the Plaintiff's claims for punitive damages generally, and under the Alabama system specifically, constitute inadequate notice to ETHEX so as to deprive this Defendant of due process of law.

51. Plaintiff's claims violate the due process provisions of the United States Constitution and the correlative provisions of the Alabama Constitution to the extent that they

seek to deprive ETHEX of procedural and substantive safeguards, including traditional defenses to liability.

52. Punitive damages cannot be sustained because of the lack in clarity in Alabama's standards for awarding punitive damages.

53. The assessment of punitive damages in this action would violate the Commerce Clause of Article 1, Section 8 of the United States Constitution to the extent that such award punishes acts or omissions which have allegedly occurred solely outside of state boundaries.

54. With respect to Plaintiff's demands for punitive damages, ETHEX specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of such damage awards which arose in the decisions of BMW v. Gore, 116 U.S. 1589 (1996) and State Farm Mut. Auto Ins. Co. v. Campbell, 123 S. Ct. 1513 (2003).

55. To the extent that Plaintiff's demands for punitive damages may result in multiple damage awards to be assessed for the same act or omission against ETHEX, such awards would contravene ETHEX's rights to due process under the due process clause of Article 1, Section 13 of the Alabama Constitution. In addition, such awards would infringe upon ETHEX's rights against double jeopardy insured by the Fifth Amendment of the United States Constitution and Article 1, Section 9 of the Alabama Constitution.

56. The procedures pursuant to which punitive damages are awarded subject ETHEX to punishment for the conduct of others through vicarious liability or through non-apportionment of damages among joint tortfeasors, in violation of the Fifth and Fourteenth Amendments to the United States Constitution and Article I §§ 1 and 6 of the Alabama Constitution.

57. Although ETHEX denies it is liable for punitive damages, ETHEX also pleads § 6-11-21 of the Code of Alabama, and such other caps on punitive damages and other damages as may be applicable.

58. Plaintiff's claims are barred to the extent that the decedent obtained or used the product at issue in a manner inconsistent with the instructions given to the decedent for normal usage.

59. Plaintiff cannot show any loss, damage, or injury by reason of any conduct or omission of ETHEX.

60. To the extent not incorporated above, ETHEX raises all defenses available under the law of Alabama or any other applicable laws.

61. ETHEX hereby gives notice that it intends to rely upon any additional defenses that become available or apparent during the course of discovery, and thus reserves the right to amend its Answer to assert such additional defenses.

WHEREFORE, ETHEX Corporation respectfully requests judgment dismissing Plaintiff's Complaint and awarding ETHEX costs, interests, attorney's fees and such other and further relief as the Court deems necessary and proper.

Respectfully Submitted:

/s/ John A. Henig, Jr.  
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**CERTIFICATE OF SERVICE**

I hereby certify that on August 21, 2009, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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